IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Appln. Of: GUMASTE

Serial No.: 09/888,837

Filed: June 25, 2001

For: PACKAGING AND DELIVERY OF PHARMACEUTICALS...

Group: 3743

Examiner: Patel, Nihir B. DOCKET: MICRODOSE 00.01

MAIL STOP APPEAL BRIEF -- PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

In connection with the above-entitled matter, enclosed please find the following:

1. Three copies of Appellant's Brief on Appeal and Appendix A under Rule 192; and

2. Credit Card Payment Authorization Form PTO-2038 in the amount of $500.00 to cover the cost of filing the Appeal Brief.

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account No. 08-1391.

Respectfully submitted,

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APPELLANT'S BRIEF ON APPEAL

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APPELLANT'S BRIEF ON APPEAL

This Brief is being filed in support of Appellant's Appeal from the Final Rejection by the Examiner to the Board of Appeals and Interferences, the Notice of which was timely filed under Certificate of Mailing on February 28, 2005.

REAL PARTY IN INTEREST

The Real Party in Interest in this Appeal is MicroDose Technologies, Inc., a Delaware corporation having its principal place of business at 4262 US Route 1, Suite 3, Monmouth Junction, New Jersey 08852. The Application has been assigned to MicroDose Technologies, Inc. by the inventor Anand V. Gumaste, and the Assignment recorded in the U.S. Patent and Trademark Office on June 25, 2001 at Reel 011936, Frame 0651.

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RELATED APPEALS AND INTERFERENCES

To the best of the knowledge of the undersigned attorney and Appellant, there are no other appeals or interferences that would directly affect, or be directly affected by, or have a bearing on, the Board's decision in the present Appeal.

STATUS OF THE AMENDMENTS

A Final Office Action was mailed on November 30, 2004. Appellants elected to file a Notice of Appeal in response to the Examiner's final rejection.

STATUS OF THE CLAIMS ON APPEAL

All pending claims, i.e., 1, 3 and 8-15, have been finally rejected and are on Appeal. The claims on Appeal are set forth in **Appendix A**, attached hereto.

BACKGROUND OF THE INVENTION

Certain diseases of the respiratory tract are known to respond to treatment by the direct application of therapeutic agents. As these agents are most readily available in dry powdered form, their application is most conveniently accomplished by inhaling the powdered material through the nose or mouth. This powdered form results in the better utilization of the medication because the drug is deposited exactly where desired and the medication's action may be required; hence, minute doses of the drug are often equally as efficacious as larger doses administered by other means, with a consequent marked reduction in the incidence of undesired side effects and medication cost.

Prior art dry powder inhalers usually have a means for introducing the drug (active drug plus carrier) into a high velocity air stream. The high velocity air-stream is used as the primary mechanism for breaking up the cluster of micronized particles or separating the drug particles

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from the carrier. Several inhalation devices useful for dispensing this powder form of medication are known in the prior art. These devices have a means for piercing or removing the top of a capsule containing a powdered medication, which upon inhalation is drawn out of the pierced or topped capsule and into the user's mouth using, e.g., the user's inhalation aided by a propeller means.

The prior art devices have a number of disadvantages which make them less than desirable for the delivery of dry powder to the lungs. Some of these disadvantages are:

- The performance of the prior art inhalers depends on the flow rate generated by the user. Lower flow rate does not result in the powder being totally de-aggregated and hence adversely affects the dose delivered to the patient;
- Inconsistency in the bioavailability of the drugs from dose-to-dose because of lack of consistency in the de-aggregation process;
- Large energy requirements for driving the electromechanical based inhalers which increases the size of the devices making them unsuitable for portable use;
- Loss of medication from opened or topped capsules; and
- Deterioration of medication in open or topped capsules due to exposure to oxygen or moisture.

SUMMARY OF THE INVENTION ON APPEAL

In accordance with the present invention, controlled aliquots or doses of a medication or drug are pre-packaged in a flexible coiled tape blister pack. The blister pack includes a frangible crowned top element which may be conical, conical with a rounded point, rounded, or other raised shape configuration, and a bottom element which may be a flat web or membrane,

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or which itself may be of shaped configuration, e.g. conical, round, dish shaped, etc. (Appellant's Specification pg. 10, lines 5-12)

In use, the bottom of the blister pack is coupled to the vibratory de-aggregator prior to or contemporaneously with piercing a top element with a piercing device such as a sharp needle. The holes thereby created form one or more apertures for enabling the release of the medication or drug contained within the blister pack. Activation of the vibratory de-aggregator drives the medication or drug from the blister pack through the holes in the top element into the inhalation device. (Appellant's Specification pg. 10, lines 13; pg. 11, lines 2-5).

The hole pattern and hole size of the apertures created in the top element is selected to provide optimization of delivery of the particular medication or drug packaged therein. The holes also can also act as filters, preventing the ejection of aggregated or agglomerated particles from the blisters, until the particles are broken up to optimal size by energy input from the vibratory de-aggregator. Thus, in the case, e.g. of a dry powder medication or drug or a liquid medication or drug, particle size and dose of the medication or drug delivered can be optimized, and tailored to the frequency of the vibratory de-aggregator. (Appellant's Specification pg. 10, lines 14-21; pg. 11, lines 1 & 2).

ISSUES PRESENTED ON APPEAL

The issue presented on Appeal is:

(1) Whether claims 1, 3, 8, 13, 14 and 15 are unpatentable under 35 USC § 103(a) as obvious from Eisele et al. (U.S. Patent 5,921,237, hereinafter Eisele et al. '237) in view of Eisele et al. (U.S. Patent No. 6,029,663, hereinafter "Eisele et al. '663");

(2) Whether claim 9 is unpatentable under 35 USC § 103(a) as obvious from Eisele et al. '237 in view of Pera (U.S. Patent 5,944,021, hereinafter "Pera");

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(3) Whether claims 10 and 11 are unpatentable under 35 USC § 103(c) as obvious from Eisele et al. '663 in view of Hendricks (U.S. Patent No. 5,699,789, hereinafter "Hendricks"); and

(4) Whether claim 12 is unpatentable under 35 USC § 103(a) as obvious from Eisele '663 in view of Shyjan (U.S. Patent 6,312,909, hereinafter "Shyjan").

THE FINAL ACTION

In finally rejecting the claims on Appeal, the Examiner has asserted numerous art rejections against the claims. In finally rejecting claims 1, 8, 13, 14 and 15 under 35 USC § 103(a) as obvious over Eisele et al. '237 in view of Eisele et al. '663, the Examiner asserts:

> Eisele discloses the applicant's invention as claimed with the exception of providing puncture holes formed in the top crown areas of the blister pack. Eisele discloses a dry powder inhaler delivery system that does provide puncture holes formed in the top crown areas of the blister pack. Therefore it would have been obvious to modify Eisele's invention by providing puncture holes formed in the top crown areas of the blister pack in order to make it easier to open. (Detailed Action, page 2, paragraph 5)

and,

In response to Appellant's argument that the portions of Eisele et al. '663 employ a rigid disk shaped blister pack, the Examiner states:

> The applicant argues that Eisele's blister pack is not a flexible coiled tape but rather a plastic carrier disk that is sufficiently rigid. The examiner disagrees. Nowhere in Eisele's reference does it state that the blister pack is sufficiently rigid as stated in the applicant's arguments. (Detailed Action, page 2, paragraph 1).

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And, the Examiner maintained in his prior Office Actions that: "Eisele discloses a dry powder inhaler that comprises an elongate flexible tape..." (Detailed Action mailed August 13, 2003, cipher 2, paragraph 2).

The remaining claims were rejected by the Examiner as obvious over either Eisele et al. '237 **OR** Eisele et al. '663 as applied to claim 1 in view of Pera, Hendricks or Shyjan.

GROUPING OF CLAIMS

Claims 1, 3, 8, 13, 14 and 15; claim 9; claims 10 and 11; and, claim 12 are grouped separately and are separately patentable.

THE REFERENCES

Eisele et al. '237

Eisele et al. '237 discloses a device for facilitating inhalation of a powdered medication that includes a round carrier disk or ring 194 carrying a blister foil ring 190 having a plurality of blisters 44 sealed with a foil seal ring 192. The foil seal ring 192 is a shear layer capable of being torn open so as to release the medication from the blister into a staging chamber using the force of gravity (Abstract, col. 3, line 60-col. 4, line 43).

Once the medication is in the staging chamber, both a patient's inhalation and a motorized fan move the medication between the staging chamber to the patient (col. 4, lines 48-63).

Eisele et al. '663

Eisele et al. '663 teaches a round carrier disk or ring 34 carrying a plurality of blister shells 34 sealed with a bottom shear layer 56. In one embodiment the shear layer 56 is designed to be torn away by a stress concentration 70 (Fig. 5B). In another embodiment the

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blisters 132 are formed with weakened sections or score lines 134 (Fig. 14) which are designed to burst under pressure of an actuator or plunger 160 (Fig. 15). In either of these embodiments, the disk carrier is designed to be oriented so that the blister contents will fall under gravity from the blister into the inhaler (Abstract).

Pera

Pera has been cited by the Examiner as teaching a method for dispensing dry powder antioxidant compounds consisting of vitamin C, vitamin E, betacarotene and lactose, using a dry powder inhaler.

Hendricks

Hendricks has been cited by the Examiner as teaching a dry powder inhaler that dispenses a medicine comprising a hormone or steroid.

Shyjan

Shyjan has been cited by the Examiner as teaching a composition and method for the diagnosis, prevention and treatment of tumor progression that uses medicine comprising a bioactive material.

ARGUMENTS ON APPEAL

The rejection of claims 1, 3, 8, 13, 14 and 15 as unpatentable under 35 USC § 103(a) as obvious over Eisele et al. '237 in view of Eisele et al. '663 is in error

Examiner rejects claims 1, 3, 8, 13, 14 and 15 as obvious over Eisele et al. '237 in view of Eisele et al. '663 stating that "Eisele discloses the applicant's invention as claimed with the exception of providing puncture holes . . . Eisele discloses a dry powder inhaler delivery system

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that does provide puncture holes." [1] However, the Examiner does not point to any teaching or motivation in either Eisele et al patent that their carrier disks are flexible and could be coiled to provide a coiled flexible tape of blisters that can be coupled with a vibratory de-aggregator as required by independent claim 1 on Appeal.

Even assuming arguendo that the Examiner meant to characterize Eisele et al '237 as teaching "an elongated flexible coiled tape" in his action, the Examiner is wrong! The blister pack of Eisele et al. '237 is not an elongate flexible coiled tape as required by Appellant's claims. Rather, the Eisele et al. '237 device is a plastic ring (Column 4, line 3) that necessarily must be sufficiently rigid to allow for the effective puncture of the blister using support tabs 196 suspended within tab slots 198 by bridges 200 (Column 3, lines 64-65), so that the tabs 196 may be pivoted to break the coil seal ring 192 sealing the blister 44 on the bottom of the blister allowing powdered drug 202 to fall into the staging area 124 (Column 4, lines 39-43).[2]

Moreover, an elongate flexible coiled tape is fundamentally different from the plastic ring of Eisele et al. '237 and provides significant advantages. First, a flexible elongate coiled tape is compact allowing more doses of medicament to be carried in a single package, while the plastic ring of Eisele et al. '237 is limited in the number of doses that can be carried without becoming too bulky. And, forming the blister pack as flexible elongate tape permits Appellant to isolate a single blister which can be interfaced and coupled to a vibratory de-aggregator. That is to say, flexible tape permits vibratory isolation. Thus, Appellant's claimed flexible tape

[1] Since it is unclear which Eisele et al. patent is the primary reference, Appellant will address the Examiner's rejection assuming both patents are the primary reference.

[2] Despite the Examiner's contention that "Nowhere in Eisele's reference does it state that the blister pack is sufficiently rigid as stated in the applicant's arguments," the rigidity of the carrier disk is a mechanical necessity given the entire disclosure of Eisele et al. '237. It seems to be a far greater logical stretch for the Examiner to characterize Eisele et al. '237 as teaching or suggesting a carrier disk that has enough flexibility that it can be morphed from a ring into a coiled tape!

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structure permits maximum energy transfer to the specific blister being worked on. A plastic ring, on the other hand, even if coupled with a vibratory de-aggregator would absorb and dampen much of the vibratory energy. Of course, Eisele et al. '237 doesn't contemplate coupling to a vibratory de-aggregator in any event. In Eisele et al. '237, an impellor is used to move the medicament between chambers.

Further with regard to the foregoing, the ability to isolate individual clusters for vibration by the use of a flexible tape as in Appellant's claimed invention also permits Appellant to optimize the frequency of the resonator for maximum material de-aggregation and ejection efficiency in a reliable and predictable manner. If Eisele et al.'s '237 blister pack disk or ring somehow were coupled to a vibratory de-aggregator, the effect would vary depending on the number of un-opened blister packs since the mass of the ring would vary depending on the number of un-opened blister packs. That is, a new fully loaded blister pack ring will dampen the vibratory energy far more than an almost emptied blister pack ring.

There are other significant structural differences between Appellant's claimed flexible coiled tape carrier and the blister pack disk or ring of Eisele et al. '237. In Eisele et al. '237 the contents of the blister cannot be "forcibly ejected from the blister when the spaced areas are interfaced coupled with the vibratory de-aggregator" as required by independent claim 1 on Appeal. Rather, in Eisele et al. '237, the contents merely fall, under gravity, when the bottom of the blister is broken away. In fact, the structure of Eisele et al. '237 is incapable of interfacing or coupling with an inhaler vibratory de-aggregator since the area at the bottom of the blister is designed to be torn or sheared away making coupling with a vibratory de-aggregator impossible. Even if Eisele et al. '237 was modified and the area between the blisters was used to couple with the vibratory de-aggregator, the plastic ring in Eisele et al. '237

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necessarily is rigid, and any vibratory energy imparted to the rigid ring would dissipate around the entire disk instead of with the blister itself.

Moreover, since gravity is an important component in the communication between the disk or ring and the inhaler in Eisele et al. '237, Eisele et al. '237 is position sensitive, i.e., the disk must be essentially horizontal to dump the contents. Thus, Eisele et al. '237 cannot be turned upside down or sideways, and may not work particularly well with a patient in a reclining position. Appellant's blister pack is not position-dependent, since it is designed to couple to a vibratory de-aggregator which acts to forcibly eject the contents from the pack.

Eisele et al. '663 also fails to teach the claimed invention.[3] Eisele et al. '663 teaches a rigid carrier disk or ring comprising either a shear layer that is designed to break under pressure or stress, or a blister having a weakened area designed to break under pressure from an actuator bursting the blister (col. 3, lines 35-40). Similarly to Eisele et al. '237, the rigidity of the ring is a mechanical necessity in order for the force concentrator 70 or the plunger 160 to function. If the ring were flexible, it would move away from the force concentration 70 or plunger 160, and defeat its purpose! Moreover, none of the above described advantages of an elongate flexible coiled tape are achieved by the rigid plastic ring of Eisele et al. '663.

Eisele et al. '663 like Eisele et al. '237 requires that the plastic ring be positioned so that the shear layer (either the crowned portion or the flat portion) is located on the bottom of the blister pack, thereby allowing the contents of the blister to be released and fall under the influence of gravity into the inhaler when the shear layer is torn.[4] Since the dry powder inhaler

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[3] Eisele et al. '237 and Eisele et al. '663 are, respectively, a continuation-in-part and a continuation of U.S. application no. 08/428,960 filed on April 24, 1995 and issued as U.S. Patent 5,662,166.

[4] The Examiner cites Eisele et al. '663 as teaching puncture holes being formed in a crowned portion of a blister. (Final Action, page 2, last paragraph). However, in Eisele et al. '663 there are no puncture holes; rather Eisele et al. '663 merely contemplates cracking or bursting open the entire bottom of the blister 132 along a single score line 134 (See Figs. 13-15 and col. 3, line 66 - col. 4, line 18).

found in Eisele et al. '663 also relies on gravity for dispensing the contents of the blister, Eisele et al. '663 is, like Eisele et al. '237, position dependent. And, the structure of Eisele et al. '663 also is incapable of interfacing or coupling with an inhaler vibratory de-aggregator as required by claim 1 on Appeal since the bottom area of the blister is designed to be torn or sheared away!

Thus, neither Eisele et al. '237 or Eisele et al. '663 alone or in combination teach or suggest a flexible coiled tape blister pack as required by Appellant's claimed invention, or the advantages thereof. Accordingly, neither claim 1, nor the several claims dependent thereon, namely claims 3, 8, 13, 14 and 15 can be said to be obvious from Eisele et al. '237 in view of Eisele et al. '663. Accordingly, the rejection of claims 1, 3, 8 and 13-15 as obvious from Eisele et al. '237 in view of Eisele et al. '663 is in error.

The rejection of claim 9 as obvious from Eisele et al. '237 in view of Pera '012 is in error

Claim 9 is dependent on claim 1. Thus, claim 9 must be construed to include all the limitations of claim 1 (35 USC § 112). The deficiencies of Eisele et al. '237 vis-à-vis claim 1 are discussed above. Pera does not supply the missing teachings to Eisele et al. '237 to achieve or render obvious claim 1 or claim 9 which is dependent thereon.

Pera has been cited as teaching dispensing an antioxidant vitamin by inhalation. However, Pera nowhere teaches or suggests any structure. Thus, the structural deficiencies of Eisele et al. '237 discussed above clearly are not supplied by Pera. Accordingly, no combination of Eisele et al. '237 and Pera can be said to achieve or render obvious claim 1 or claim 9 which depends thereon, and, the rejection of claim 9 as obvious from Eisele et al. '237 in view of Pera is in error.

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The rejection of claims 10 and 11 as obvious from Eisele et al. '663 in view of Hendricks '789 is in error.

Claims 10 and 11 are dependent on claim 1. The deficiencies of the primary reference Eisele et al. '663 vis-à-vis claim 1 are discussed above. It is not seen that Hendricks supplies the missing teachings to Eisele et al. '663 to achieve or render obvious claim 1 or claims 10 and 11 which depend thereon. Hendricks has been cited as teaching a dry powder inhaler in which the material comprises a hormone or steroid. However, Hendricks' inhaler is radically different in construction from Eisele et al. '663. Nowhere is there any teaching or suggestion within Hendricks as to how the Eisele et al. '663 inhaler should be modified, i.e., to form a flexible coiled tape blister pack as required by Appellant's claims. Accordingly, no combination of Eisele et al. '663 and Hendricks can achieve or render obvious claim 1 or claims 10 and 11 which depend thereon, and, the rejection of claims 10 and 11 as obvious from Eisele '663 in view of Hendricks also is in error.

The rejection of claim 12 as obvious from Eisele et al. '663 in view of Shyjan '909 is in error

Claim 12 is dependent on claim 1. The deficiencies of the primary reference Eisele '663 are discussed above. It is not seen that Shyjan supplies the missing teachings to Eisele '663 to achieve or render obvious claim 1 or claim 12 which depends thereon. It is, frankly, not clear from the Examiner's rejection as to what Shyjan has been cited as other than as teaching a bioactive material. Shyjan, like Pera contains absolutely no teaching or disclosure of inhaler structure or any form of blister back for use with an inhaler structure. Thus, no combination of Eisele '663 and Shyjan could be said to achieve or render obvious claim 1 or

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claim 12 which depends thereon. Accordingly, the rejection of claim 12 as obvious from Eisele '663 in view of Shyjan also is in error.

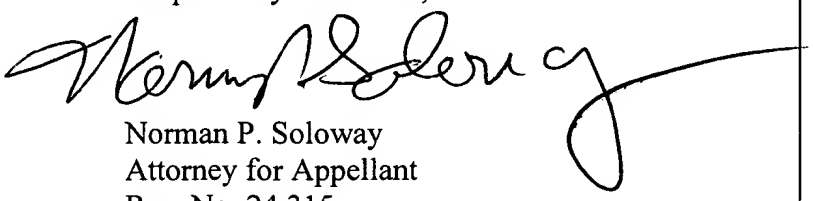
SUMMARY

In summary, it is respectfully submitted that the claimed invention is clearly patentably distinguished over the prior art of record. None of the prior art of record, whether taken singly or in combination, discloses or remotely suggests a blister formed on an elongate flexible tape that is capable of coupling with a vibratory de-aggregator. Thus, since these features of Appellant's claimed invention are nowhere disclosed or suggested in any of the prior art of record, it is respectfully submitted that the rejection of the claims on Appeal under 35 USC §103 are in error.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Examiner's Rejection of the subject Application be reversed in all respects.

Respectfully submitted,



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APPENDIX A - CLAIMS ON APPEAL

Claim 1: A blister pack for use with inhalation therapy inhalers equipped with a vibratory de-aggregator, comprising a first element comprising an elongate flexible coiled tape having spaced areas for interfacing and coupling with a inhaler vibratory de-aggregator, and a frangible second element overlying the first element and defining a plurality of spaced top crowned areas located over said first element spaced areas, and containing powder or liquid material, wherein the contents of the blister are forcibly ejected from the blister through puncture holes formed in the top crown areas when the spaced areas are interfaced coupled with a vibratory de-aggregator.

Claim 3 : A blister pack according to claim 1, wherein said top crowned areas are shaped as inverted cones.

Claim 8: A blister pack according to claim 1, wherein said material comprises a medication.

Claim 9: A blister pack according to claim 1, wherein said material comprises a vitamin.

Claim 10: A blister pack according to claim 1, wherein said material comprises a hormone.

Claim 11: A blister pack according to claim 1, wherein said material comprises a steroid.

Claim 12: A blister pack according to claim 1, wherein said material comprises a bioactive material.

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Claim 13: A blister pack according to claim 1, wherein a size and number of puncture holes together with volume formed by the blister pack are optimized for de-aggregation and aerosolization of material in the blister pack.

Claim 14: A blister pack according to claim 1, wherein a height and shape of the blister pack is optimized for de-aggregation and aerosolization of material in the blister pack.

Claim 15: A blister pack according to claim 1, wherein an interface to a vibrator is optimized for optimum coupling of the energy into the blister pack for de-aggregation and aerosolization of material in the blister pack.

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